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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,878	09/08/2003	Mark W. Kroll	A03P1062US04	2626

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PACESETTER, INC.
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EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/657,878	KROLL ET AL.	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 September 2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/7/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner acknowledges the amendments received 07 June 2006. Claims 1-13 are pending.

Double Patenting/Terminal Disclaimer

2. The terminal disclaimer filed on 07 June 2006 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of 08 September 2003 has been reviewed and is accepted. The terminal disclaimer has been recorded.

3. In view of the terminal disclaimer, the provisional rejection of claims 1-5, 8-11 and 13 on the grounds of nonstatutory obviousness type double patenting is withdrawn.

Claim Objections

4. In view of the amendments to the claims, the objection to claim 7 is withdrawn.

Claim Rejections - 35 USC § 102

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Applicant's arguments, see "Remarks," pages 6-10 filed 07 June 2006, with respect to claims 1-3, 6, 8-9 and 13 have been fully considered and are persuasive, with regards to the Mouchawar and Andersson references failing to disclose a backup pulse capture detection unit. The rejection of claims 1-3, 6, 8-9 and 13 has been withdrawn.

7. With regards to the applicant's argument that Mouchawar's system does not disclose or suggest a capture-based ventricular tachycardia detection unit operative to detect a ventricular tachycardia based upon LOC, the examiner respectfully disagrees. It is to be noted that Mouchawar discloses (col. 12, lines 21-29) preventing inappropriate tachycardia detection by "preventing the atrial sensing circuitry or the ventricular sensing circuitry from sensing events associated with the evoked response that normally follow the stimulation pulse." This may lead to inappropriate delivery of anti-tachycardia therapies. If capture of a stimulation pulse is not verified following deliver of the pulse (col. 14, lines 18-21) the automatic capture method will enter a capture search mode, in which (col. 16, liens 56-67) an intrinsic response of tachycardia or fibrillation is detected. If no arrhythmia is detected, the capture verification method calls upon the capture search method to initiate search for the minimum stimulation energy required to achieve capture on the next stimulation cycle.

8. The examiner considers this to be a capture-based atrial tachycardia detection unit that detects tachycardia based on loss of capture. The applicant claims that the tachycardia detection is not based on loss of capture. However, in the course of the capture search mode, arrhythmias such as tachycardia are detected.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mouchawar et al (U.S. 6,553,259) in view of Bradley et al (U.S. 2003/0208241). Mouchawar discloses (col. 5, lines 20-24; Figs. 1-2) "an implantable cardiac stimulation device including a method for sensing cardiac events and delivering both high and low voltage stimulation therapies for appropriately treating bradycardia, tachycardia, or fibrillation. One method of therapy delivery includes 1) sensing for cardiac activity within a cardiac chamber during a defined escape interval; 2) when intrinsic cardiac activity is not detected within the given escape interval, delivering a stimulation pulse for the purpose of stimulating the cardiac chamber to contract at a desired rate; 3) verifying that the delivered stimulation pulse produced an evoked response by sensing during an alert interval following a short refractory period; 4) if no evoked response is detected during the alert interval, sustaining the desired stimulation rate by delivering a back-up stimulation pulse; 5) whenever a back-up stimulation pulse is required, performing a capture search for determining the minimum pulse energy needed to reliably achieve capture, and 6) adjusting the programmed stimulation energy to a level safely above the newly determined capture energy. When the automatic capture function is enabled, the stimulation device initiates a stimulation refractory period, upon the expiration of which, the stimulation device sets a sensing threshold to an evoked response threshold." Mouchawar further discloses (col. 4, lines 47-55) "an implantable cardiac stimulation device possessing pacing, cardioversion and defibrillation functions and automatic capture capabilities, for automatically verifying capture during stimulation operations and, as necessary, automatically delivering back-up stimulation pulses when capture is

lost, and subsequently adjusting the stimulation energy to a level safely above that needed to achieve capture." Mouchawar discloses the claimed invention except for a capture detection unit operative to detect loss of capture of both primary pacing pulses and backup pacing pulses. Bradley however discloses (par. 0052; Fig. 3) detection of a possible second consecutive LOC (loss of capture) after a backup stimulation pulse, and the possible delivery of another pulse of greater magnitude until capture is detected. Bradley and Mouchawar both disclose methods and systems for application of stimulation pulses to ensure capture of the heart. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Mouchawar's tachycardia detection unit with Bradley's backup pulse capture detection unit in order to avoid repeated LOC with needless stimulation pulses.

Regarding claim 2, Mouchawar discloses (col. 17, line 67; col. 18, lines 1-5) "if no evoked response is detected, a back-up stimulation pulse, preferably equal to 1.5 to 2 times the current pulse amplitude, is delivered (at step 527), and the method (500) returns (to step 505) to verify that the pulse width has not reached a maximum, and then continues to increase the pulse energy by incrementing the pulse width (step 515)." The examiner considers this to be an atrial tachycardia detection unit that detects atrial tachycardia based on loss of capture of both an atrial pacing pulse delivered at less than the maximum pulse magnitude and a subsequent backup pulse that is delivered at the maximum pulse magnitude.

Regarding claim 3, Mouchawar discloses (col. 18, lines 59-63) "automatic threshold test mode or method (900), is illustrated in the flow of FIG. 13. Automatic threshold testing may be performed upon a programmed command or periodically, such as daily weekly or monthly, or upon an event-trigger from microprocessor (60)." The examiner considers this to teach a stimulation threshold search operative to determine a capture threshold for primary pacing pulses.

Regarding claim 4, Bradley discloses (par. 0052) "if, however, any of the overdrive pacing pulses are not captured by the atria (i.e. a LOC has been detected) then, following step 204, a backup pacing pulse is delivered at step 210. The backup pulse is set to the HOM voltage of, for example, 4.5V and is delivered 40 ms after the pulse that failed to evoke capture. The Consecutive LOC Counter is incremented at step 211. If the LOC is a first LOC, processing simply continues at step 202 for further overdrive pacing. However, upon detection of a second consecutive LOC during the

dwell time, the overdrive unit performs an automatic capture threshold detection search at step 212 using the technique of FIG. 4 to set a new capture threshold and a new pulse magnitude. Thereafter, the next sequence of overdrive pacing pulses is generated using the new pulse magnitude. Thus two consecutive LOCs trigger a capture threshold detection search. A capture detected subsequent to a first LOC will reset the Consecutive LOC Counter at step 205 so that the next LOC will not immediately trigger the capture threshold detection search."

Regarding claim 5, Mouchawar discloses (col. 19, lines 5-10) "the threshold test mode then progressively decreases the stimulation pulse energy until a threshold test criterion is satisfied (at decision step 910). For example, a specified number of cycles in which the current pulse energy fails to capture the paced chamber, preferably two consecutive capture failures." The examiner considers this to be an atrial stimulation threshold search unit that is activated if a first number of delivered pulses.

Regarding claim 6, Mouchawar discloses (col. 5, lines 20-23) "an implantable cardiac stimulation device including a method for sensing cardiac events and delivering both high and low voltage stimulation therapies for appropriately treating bradycardia, tachycardia, or fibrillation."

Regarding claim 7, the examiner considers the method illustrated in Figure 3 in the Bradley reference to illustrate preventive overdrive pacing. See also paragraph 0052.

11. Claims 8-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersson et al (U.S. 5,846,264) in view of Bradley et al (U.S. 2003/0208241). Regarding claims 8-9 and 13, Andersson discloses (col. 1, lines 40-50) "some pacemakers have means which not only test for successful capture but also, in the event of loss of capture, are capable of generating a back-up pulse shortly after the failure in order to sense an evoked response from a preceding stimulus. The back-up pulse is supplied from the stimulation circuit, which contains a stimulation capacitor. In order to ensure capture, the energy supplied in the back-up pulse is discharged at the maximum permissible voltage, usually around 4.5 volts. Thus immediately after each stimulation pulse has been discharged, the stimulation capacitor is charged to its maximum voltage of around 4.5 volts, so as to be able to produce a back-up pulse if one is required." Andersson further discloses (col. 2, lines 30-40) a pacemaker that

"includes an output stage (1) connected to a heart, an evoked response detector (5), also connectable to the heart (2), and a pacing control unit (3) which operates the output stage and the evoked response detector. In one embodiment of the invention, shown in FIG. 1, the output stage of the pacemaker (4) has, in addition to the usual stimulation capacitor (C1) and compensation capacitor (C2), at least one back-up pulse capacitor (C3). In order to stimulate the heart, the stimulation capacitor, which typically has a capacitance of 10 microfarads, is charged by a charge pump to a voltage determined by the physician or the manufacturer, which could be, for example, 1.5 volts. When the pulse is to be sent to the heart, switch (S1) is closed by the pacing control unit and current flows through the output circuit to the heart via the compensation capacitor. Compensation capacitor has a capacitance of typically 5 microfarads, and it is charged by the current passing through it." The examiner considers this to be delivering primary pacing pulses to the ventricles of the heart, verifying capture of the primary pacing pulses, delivering a backup pulse to the ventricles upon detection of a loss of capture of a primary pacing pulse, verifying capture of the ventricular backup pacing pulse and detecting a ventricular tachycardia based upon detection of loss of capture of a backup pulse in the ventricles. Pulses are delivered at a pulse magnitude less than a predetermined maximum pulse magnitude and the backup pulse is delivered at the maximum pulse magnitude. Andersson discloses the claimed invention except for a capture detection unit operative to detect loss of capture of both primary pacing pulses and backup pacing pulses. Bradley however discloses (par. 0052; Fig. 3) detection of a possible second consecutive LOC (loss of capture) after a backup

stimulation pulse, and the possible delivery of another pulse of greater magnitude until capture is detected. Bradley and Andersson both disclose methods and systems for application of stimulation pulses to ensure capture of the heart. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Andersson's backup pulse stimulator with Bradley's backup pulse capture detection unit in order to avoid repeated LOC with needless stimulation pulses.

12. Regarding claim 10, Bradley discloses (par. 0052) performing a stimulation threshold search using the stimulation threshold search unit if a primary pacing pulse is not captured but a backup pulse is captured.

13. Regarding claim 11, the examiner considers the method illustrated in Figure 3 of the Bradley reference to illustrate preventive overdrive pacing. See also paragraph 0052.

14. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Andersson et al (U.S. 5,846,264) in view of Bradley et al (U.S. 2003/0208241) and in further view of Olson et al (U.S. 6,731,978). Andersson and Bradley disclose the claimed invention except for delivering shock therapy to the ventricles if both a primary pacing pulse and a backup pulse are not captured in the ventricles. Olson however discloses (col. 16, lines 34-48) "the processor determines which of the various available rules have all of their respective clauses satisfied." If "one, more than one, or no rules may have their causes all satisfied. If more than one rule is true or "fires" the rule of highest priority is selected, leading to a rhythm classification corresponding to that rule. In response to the classification of the rhythm, the device delivers therapy or prevents delivery of therapy, depending upon the rhythm identified. In the absence of any rules

being identified, the device withholds anti-tachycardia therapy. If the device is programmed to provide bradycardia backup pacing, it continues to do so. If not, the device simply continues to monitor the rhythm of the heart, until one or more rules fire." Andersson, Bradley and Olson all teach treatment of arrhythmias in the heart. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Andersson's overdrive pacing system with Bradley's backup capture detection unit and with Olson's antitachycardia pacing in order pace a heart in the event of loss of capture.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 8.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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